

510(k) SUMMARY

JUN 16 2014

DATE

May 27, 2014

PRODUCT, CLASSIFICATION NAME

Device name: Planmeca Romexis
Common name: System, Image Processing, Radiological
Classification: Class II
Classification name: Imaging Processing System, LLZ, 21 CFR 892.2050

SUBMITTED BY

Planmeca Oy
Asentajankatu 6
00880 Helsinki, Finland
Phone: +358 20 7795 500
Fax: +358 20 7795 396
Contact person: Mr. Lars Moring

U.S DESIGNATED AGENT

Planmeca USA Inc.
100 North Gary Avenue, Suite A
Roselle, IL 60172
Phone: (630) 529 2300
Fax: (630) 529 1929
Contact person: Bob Pienkowski

DEVICE DESCRIPTION

Planmeca Romexis is a modular imaging software for dental and medical use. It is divided into modules to provide user access to different workflow steps involving different diagnostic views of images. Patient management screen with search capabilities lets users to find patients and identify correct patient file before starting work with a patient. After creating or selecting patient, new images can be acquired using select Planmeca X-ray units.

Planmeca Romexis is capable of processing and displaying 2D images in different formats and 3D CBCT images in DICOM format. 3D CBCT images can be viewed in near real-time multi projection

reconstruction (MPR) views. 2D and 3D image browsers are provided to allow user access to relevant images. Typical image enhancement filters and tools are available to assist the user in making diagnosis but original exposure is always kept in the database for reference.

INDICATIONS FOR USE

Planmeca Romexis is a medical imaging software, and is intended for use in dental and medical care as a tool for displaying and visualizing dental and medical 2D and 3D image files from imaging devices, such as projection radiography and CBCT. It is intended to retrieve, process, render, diagnose, review, store, print, and distribute images.

It is also a preoperative software application used for the simulation and evaluation of dental implants. The software includes monitoring features for Planmeca devices for maintenance purposes. It is designed to work as a stand-alone or as an accessory to Planmeca imaging and Planmeca dental unit products in a standard PC. The software is for use by authorized healthcare professionals.

Planmeca Romexis software is:

- Not intended for capturing optical impressions for dental restorations.
- Not intended for optically scanning stone models and impressions for dental restorations.
- Not intended for optically scanning intraoral preparations for use in designing implants and/or abutments.
- Not intended for optically scanning intra-orally for use in orthodontics.
- Not intended for mammography use.

PREDICATE DEVICES

K123519	Anatamage	InVivoDental
K061035	Televere Systems	TigerView

TECHNOLOGICAL CHARACTERISTICS

Both Planmeca Romexis and the predicate device InVivoDental are software applications with similar characteristics related to managing of 3D image files. Both applications are meant for use with standard PC hardware and include similar major functionality related to display, processing, visualization and sharing of dental and medical 3D image files, such as multiplanar views, volume rendering view, measurements, implant planning, airways visualization, TMJ module, virtual cephalometric and panoramic images and sharing of image files with a viewer.

The main difference is that Planmeca Romexis lacks the capability to make surgical or orthodontic planning.

Both Planmeca Romexis and the predicate device TigerView Professional are software applications with similar characteristics related to managing of 2D image files. Both applications are meant for use with standard PC hardware and include similar major functionality related to display, editing, reviewing, storing, printing, and distributing of 2D image files, such as annotations, adjustments, integration with

practice management systems and distribution of images in Picture Archiving and Communication System (PACS) environment.

NON-CLINICAL TEST RESULTS

The following quality assurance measures were applied to the development of the Software:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Performance testing (Verification)
- Safety testing (Verification)
- Final acceptance testing (Validation)
- Bench testing to compare with predicate software

Testing confirmed that Planmeca Romexis is stable and operating as designed. Testing also confirmed that Planmeca Romexis has been evaluated for hazards and that the risk has been reduced to acceptable levels.

The non-clinical bench-testing of Planmeca Romexis with predicate software was performed by comparison of images rendered by Planmeca Romexis and the predicate software InVivoDental of Anatomage. This confirms that both software applications are equally effective in performing the essential functions and provide substantially equivalent clinical data.

SUMMARY

Based on the intended use, product, performance, and testing information provided in this notification, the subject device has been shown to be substantially equivalent in technology, functionality, and indicated use to the currently marketed predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 16, 2014

Planmeca Oy
% Mr. Lars Moring
Regulatory Affairs Manager
Asentajankatu 6
Helsinki 00880
FINLAND

Re: K140713
Trade/Device Name: Planmeca Romexis
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 28, 2014
Received: June 2, 2014

Dear Mr. Moring:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

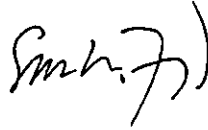
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K140713

Device Name
Planmeca Romexis

Indications for Use (Describe)

Planmeca Romexis is a medical imaging software, and is intended for use in dental and medical care as a tool for displaying and visualizing dental and medical 2D and 3D image files from imaging devices, such as projection radiography and CBCT. It is intended to retrieve, process, render, diagnose, review, store, print, and distribute images.

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- Not intended for mammography use.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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PRASStaff@fda.hhs.gov

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.